UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES LISTED ON EXHIBIT 1**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE AND OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN OPINIONS OF ABBAS SHOBEIRI, M.D.

Plaintiffs, identified in Ex. 1 attached hereto, submit their response and opposition to Defendants' Motion to Exclude Certain Opinions of Abbas Shobeiri, M.D.

INTRODUCTION

Dr. Shobeiri is a professor of Obstetrics and Gynecology at George Washington University and Virginia Commonwealth University.[1] He is a practicing surgeon and is board certified in Obstetrics/Gynecology and Female Pelvic Medicine and Reconstructive Surgery.[2] Dr. Shobeiri previously served as an Assistant and then Associate Professor at the University of Oklahoma Health Services Center ("OUSHC") in the Department of Obstetrics & Gynecology from 2002 until 2013.[3] During his tenure at OUSHC, he was the Division Chief for Female Pelvic Medicine and Reconstructive Surgery and Medical Director of the OU Women's Pelvic &

[1] S. Abbas Shobeiri Curriculum Vitae, Case 2:12-md-02327 Document 2073-2 Filed 04/21/16 (attached as Ex. 2); Deposition of Abbas Shobeiri, M.D., 2/27/16 at 24:5-18 (Excerpts attached as Ex. 3). Defendants incorrectly assert that Dr. Shobeiri is currently practicing in Oklahoma. Defendants' Memorandum at p. 1.
[2] Ex. 2 at p. 3.
[3] *Id*. at p. 4.

Bladder Health National Center of Excellence.[4] Dr. Shobeiri has been involved as lead author or co-author in the publication of more than 90 articles relating to the pelvic region of the human body, including articles related to his research in the area of 3D pelvic floor ultrasonography and levator ani anatomy.[5] While a professor at OUSHC, he developed a curriculum for OB/GYN residents and medical students and provided leadership training courses for medical students during their third-year OB/GYN rotation.[6] He also proctored medical students during abdominal and pelvic dissection.[7] Dr. Shobeiri has edited and written book chapters on subjects including pelvic floor anatomy, pelvic floor trauma; pelvic floor ultrasound, classification of meshes, and endovaginal ultrasonography.[8] He served as Editor for Practical Pelvic Floor Ultrasonography 2015 and has contributed to several chapters of that book.[9]

Dr. Shobeiri has performed approximately 100 transobturator sling procedures, with approximately 50 of those procedures involving the Ethicon TVT-O product.[10] He stopped using the TVT-O sometime in 2012 or 2013 due to complications experienced by his patients.[11]

LEGAL STANDARDS

Plaintiffs will not repeat in full the applicable standards relating to the admission of expert testimony as this Court is well-versed in those standards. For the purposes of this opposition, as this Court has recognized "[t]he proponent of expert testimony does not have the burden to "prove anything" but must "come forward with evidence from which the court can

[4] *Id*. at p. 5.
[5] *Id*. at p. 8-15.
[6] *Id*. at p. 5.
[7] *Id*. at p. 5.
[8] *Id*. at p. 16-18.
[9] *Id*. at p. 17.
[10] Ex. 3 at 19:15 - 22:3.
[11] Ex. 3 at 16:22 - 19:10.

determine that the proffered testimony is properly admissible."[12] Additionally, this Court has noted it "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'"[13]

I. Dr. Shobeiri is Qualified to Provide Opinions that the Product is Defectively Designed.

Defendants' argument that Dr. Shobeiri is not qualified to testify that Defendants' mesh products are defectively designed is without merit. Defendants limit their challenge to Dr. Shobeiri's design defect opinions to his opinion that the TVT-O and Prolift mesh "are defectively designed because their polypropylene mesh can shrink, contract or deform" and the "alleged defect is that the mesh can coil, rope and fray."[14] Defendants have not asserted a challenge to the following opinions concerning the defects of the TVT-O products:

2. The blind passage of synthetic mesh arms through muscle and densely-innervated tissue, resulting in tissue damage and trauma.

5. The difficulty or impossibility of removing the entire device when complications warrant.

6. The need for multiple surgeries to remove mesh.

7. The chance of persistent symptoms, especially pain, even after the device has been removed.

8. The products can result in late onset of complications that may occur indefinitely into the future.

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[12] *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W.Va. 2013) (quoting *Maryland Cas. Co. v. Therm–O–Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998)).

[13] *In re C.R. Bard*, 948 F. Supp. 2d at 601 (quoting *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006)); *see also Maryland Cas. Co.*, 137 F.3d at 783.

[14] Defendants' Memorandum at p. 3.

9. The products cause chronic pain syndromes (resulting from nerve entrapment, scarring, mesh deformation and contraction and inflammation), that are often extremely difficult to treat.[15]

Contrary to Defendants' assertions, Dr. Shobeiri cites to numerous articles that support his opinion that mesh can "shrink, contract, or deform" and "coil, rope, and fray." Defendants contend because Dr. Shobeiri could not "identify any particular study" supporting his opinions, his opinions are not supported and are merely *ipse dixit*.[16] The truth is that Dr. Shobeiri testified that "there are a lot of articles supporting this. I have to see the actual articles to put it out for you" and "I think they're all in the references that we have given to you."[17] Moreover, contrary to Defendants' assertion, Dr. Shobeiri's report, in numerous footnotes, identified specific articles from his reference list that supported his opinions.[18] Additionally, Dr. Shobeiri, in formulating his opinions, considered and critically assessed literature that was favorable and unfavorable to his opinions.[19] Defendants argument that Dr. Shobeiri "cites no studies for his opinions that mesh contracts" is easily swept away by the examination of just a few of the articles cited in the footnotes in his reports. For instance, Dr. Shobeiri specifically cites the following articles, which address contraction, shrinkage and/or folding/roping/curling of mesh:

- Haylen, B. T., *et al.* (2011). *"An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery."* Neurourol Urodyn 30(1): 2-12;[20]

[15] Rule 26 Expert Report of Abbas Shobeiri (Wave 1/ TVT-O Cases) at p. 22-23 (attached as Ex. 4); *see also* Rule 26 Expert Report of Abbas Shobeiri (Prolift) at p. 21-22 (attached as Ex. 5).
[16] Defendants' Memorandum at p. 3-5.
[17] Ex. 3 at 106:2-4, 106:23-24.
[18] Ex. 4 at p. 15-22, n. 3-23; Ex. 5 at p. 14-21, n. 2-23; Ex. 3 at 157:17 – 163:21.
[19] Ex. 3 at 171:3-6.
[20] Attached as Ex. 6 ("*Prominence*: Parts that protrude beyond the surface (e.g., due to wrinkling or folding with no epithelial separation." Ex. 6 at p. 4).

- Lee, D., *et al.* (2014). "*Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes."* Expert Rev Med Devices: 1-16;[21]
- Rogo-Gupta, L. and S. Raz Pain Complications of Mesh Surgery. Complications of Female Incontinence and Pelvic Reconstructive Surgery;[22]
- Marcus-Braun, N. and P. von Theobald (2010). *"Mesh removal following transvaginal mesh placement: a case series of 104 operations."* Int Urogynecol J 21(4): 423-430;[23]
- Feiner, B. and C. Maher (2010). "*Vaginal mesh contraction: definition, clinical presentation, and management."* Obstet Gynecol 115(2 Pt 1): 325-330;[24] and
- Manonai, J., G. Rostaminia, L. Denson, and S. A. Shobeiri. "*Clinical and Ultrasonographic Study of Patients Presenting with Transvaginal Mesh Complications."* Neurourol Urodyn (Jan 25 2015).[25]

In addition, Dr. Shobeiri also cited the following articles in his materials list relating to contraction of mesh implants.

- Letouzey, et al., "*Ultrasound Evaluation of Polypropylene Mesh Contraction at Long Term after Vaginal Surgery for Cystocele Repair."* Abstracts / Journal of Minimally Invasive Gynecology I6 (2009) SI—S5I.[26]
- Tunn, et al. *"Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele."* Ultrasound Obstet Gynecol 2007; 29:449–452.[27]

[21] Attached as Ex. 7 ("Vaginal: No epithelial separation Include prominence (e.g. due to wrinkling or folding), mesh fiber palpitation or contraction (shrinkage)" Ex. 7 at p. 11).
[22] Attached as Ex. 8 ("Mesh location, direction, size, extrusion, penetration and folding may be identified by ultrasound." Ex. 8 at p. 101).
[23] Attached at Ex. 9 ("Malposition of the mesh can be diagnosed during vaginal examination when the mesh is felt shifted on one side, and it can also be diagnosed by ultrasound. Shrinkage of the mesh is a complication described widely that can result in severe deformation of the vagina cause dyspareunia, defecatory, and urinary dysfunction." Ex. 9 at p. 428.)
[24] Attached as Ex. 10 ("Vaginal mesh contraction is a serious complication after pelvic organ prolapse repair using armed polypropylene mesh. It is characterized by severe vaginal pain and dyspareunia and on vaginal examination focal tenderness over contracted portions or the mesh." Ex. 10 at p. 330).
[25] Attached as Ex. 11 ("Mesh contraction is a serious complication after pelvic organ prolapse repair using polypropylene mesh" and "Persistent pain . . . . may be the consequence of nerve entrapment or mesh contraction." Ex. 11 at p. 410).
[26] Attached as Ex. 12 ("ultrasound reconstruction has been showed a mean contraction of 30%" Ex. 12 at p. 3).
[27] Attached as Ex. 13 ("The mesh lengths measured sonographically in vivo were much shorter than were the implanted mesh lengths" Ex. 13 at p. 4).

Dr. Shobeiri's opinions are supported by peer-reviewed medical literature cited specifically in his report and also on his literature reference list. Dr. Shobeiri's opinions are based upon published medical literature, including publications related to his own clinic practice treating patients with "transvaginal mesh complications."[28] His report explains the methodology employed when evaluating mesh complications with 3D Ultrasonography, which is referenced in the literature and Dr. Shobeiri utilizes in his practice of medicine.[29] Additionally, his opinions are based on his own clinical practice where he has found that TVT-O mesh rolls, frays and curls.[30] His opinions are not merely *ipse dixit* and his opinions are based upon a reliable methodology and are admissible. This Court rejected a similar argument as to Dr. Blaivas in *Tyree*, where the Court concluded that the fact that Dr. Blaivas could not point to a specific article during his deposition did not make his opinions excludable under *Daubert*.[31]

Defendants assert that Dr. Shobeiri is not qualified to provide opinions that the TVT-O and Prolift products are defectively designed because he is not a biomaterials expert and not an expert in biocompability issues.[32] Defendants also assert these same claims as a basis for excluding Dr. Shobeiri's opinions concerning the adequacy of the warnings provided for both product.[33] Plaintiffs will only address these claims in this section to avoid duplication of the argument against Defendants' assertions to Dr. Shobeiri's qualifications. Dr. Shobeiri is qualified to testify that both products were defectively designed and the warnings provided by both products were not adequate. While Dr. Shobeiri is not a "biomaterials engineer,"[34] he has

[28] Ex. 4 at p. 16-17 and n. 7; Ex. 5 at p. 16-18 and n. 8.
[29] Ex. 4 at p. 16-18; Ex. 5 at p. 16-18.
[30] Ex. 3 at 108:19-109:5.
[31] *Tyree v. Boston Scientific Corp.*, 2014 WL 5320566, *45 (S.D.W. Va. 2014).
[32] Defendants' Memorandum at p. 3-4.
[33] Defendants' Memorandum at p. 8.
[34] Ex. 3 at 136:1-3.

been involved with the design of a polypropylene mesh product for submission to the FDA for approval.[35] He testified that the product at issue differed from the TVT-O in the way it was woven and it does not fray or roll like the TVT-O product.[36] His involvement in the design of this product included the study of the anatomical course, in cadavers and live patients, and conducting trials of the product.[37] In addition to his work on the design of a polypropylene mesh product, Dr. Shobeiri has implanted approximately 50 TVT-O products so he has clinical experience with the product at issue. He also relies on numerous peer-reviewed medical articles to support his opinions relating to complications caused by the TVT-O and Prolift products.[38] Additionally, Dr. Shobeiri has co-authored peer-reviewed articles concerning mesh complications.[39]

In *Tyree*, this Court rejected a similar challenge to Dr. Ostergard's qualifications to testify about design issues and held:

> It is difficult to deride Dr. Ostergard's qualifications generally. He has performed thousands of pelvic organ prolapse surgeries. He has used a variety of synthetic and biologic materials in pelvic reconstruction, including polypropylene mesh. He has extracted polypropylene mesh products from patients. He has treated them for

[35] Ex. 3 at 31:18 – 35:1.
[36] Ex. 3 at 33:3-6.
[37] Ex. 3 at 35:11-15.
[38] Ex. 4 at p. 15-22, n. 3-23; Ex. 5 at p. 14-21, n. 2-23; Ex. 3 at 157:17 – 163:21.
[39] Manonai, J., G. Rostaminia, L. Denson, and S. A. Shobeiri. *"Clinical and Ultrasonographic Study of Patients Presenting with Transvaginal Mesh Complications."* Neurourol Urodyn (Jan 25 2015)(Ex. 11); Santoro GA, Wieczorek AP, Dietz HP, Mellgren A, Sultan AH, Shobeiri SA, *et al. State of the art: an integrated approach to pelvic floor ultrasonography*. Ultrasound ObstetGynecol. 2011;37:381–96. In addition to his authorship of these articles, Dr. Shobeiri has been a co-author of other articles relating to the use of 3D endovaginal ultrasound techniques for assessment of pelvic flor conditions. *See* Ex. 4 at p. 17, n. 8. During his career, Dr. Shobeiri has been an author or co-author of 97 peer-reviewed published articles, including articles related to pelvic mesh removal, mesh complications and anatomy issues related to pelvic mesh products. Ex. 2 at p. 8-15. He has authored or co-authored several additional articles that are in progress or have been submitted for peer-review publication, including article relating to mesh complications and transobturator tape syndrome. Ex. 2 at p. 15-16. *See* Ex. 3 at 90:12 – 91:10.

> mesh-related complications. He also performed preliminary theoretical work on a new pelvic mesh device for American Medical Systems.
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> Dr. Ostergard has conducted scanning electron microscope imaging of mesh. He is also participating in an on-going study of its degradation characteristics in conjunction with his University of Louisville colleagues. Finally, Dr. Ostergard has published, in a peer reviewed setting, on a variety of synthetic and natural materials used in pelvic reconstruction surgery dating back to the 1980s. I conclude that Dr. Ostergard's qualifications are sufficient to testify about polypropylene.[40]

Dr. Shobeiri's qualifications and experience are similar. While he has not performed thousands of transobturator procedures, he has performed approximately 100 such procedures, including approximately 50 procedures involving the TVT-O product. He has treated patients for mesh complications, frequently using 3D Ultrasonography for diagnosis of such complications. He has been involved with a mesh manufacturer in the design of a polypropylene mesh product. Dr. Shobeiri is qualified to testify about design issues related to the TVT-O and Prolift products.

Defendants' Motion to Exclude Dr. Shobeiri's design defect opinions is due to be denied.

II. Dr. Shobeiri's Opinions Concerning Safer Alternatives are Reliable and Relevant.

Defendants' argument that Dr. Shobeiri's opinions concerning safer alternatives are unreliable and irrelevant is without merit.

First, Defendants assert that Dr. Shobeiri does not have any support for his opinions that a retropubic sling is a safer alternative to a TVT-O or that an abdominal or laparoscopic sacrocolpopexy is a safer alternative to a Prolift product.[41] As to a safer alternative for the TVT-O, Defendant argues that Dr. Shobeiri admitted that there is medical literature stating the TVT-O is equivalent to the retropubic sling.[42] However, Defendants conveniently ignore Dr. Shobeiri's

[40] *Tyree*, 2014 WL 5320566 at * 35-36.
[41] Defendants' Memorandum at p. 5.
[42] Defendants' Memorandum at p. 5.

testimony that there is medical literature stating that the TVT-O is not as safe as a retropubic sling.[43] As to mesh implanted during an abdominal or laparoscopic sacrocolpopexy, Defendants did not even question Dr. Shobeiri about this safer alternative during his deposition. However, in his Prolift report, Dr. Shobeiri explains mesh implanted through these types of procedures and why the procedures are safer than a Prolift product.[44] Dr. Shobeiri also cites specific medical literature he relied on to formulate his opinion.[45]

Second, regardless of the cases cited by Defendants concerning an alternative procedure not being sufficient to establish an alternative design, this Court has previously concluded that "mesh constructed from native tissue" constituted sufficient evidence of an alternative design in *Lewis*.[46] Dr. Shobeiri's opinions and testimony establish a safer alternative for the TVT-O in the form of a retropubic sling because it avoids the transobturator space and complications arising from implanting mesh in that nerve-rich area of the body.[47] As to a safer alternative to the Prolift, Dr. Shobeiri's report establishes that mesh implanted during an abdominal or laparoscopic sacrocolpopexy is a safer alternative. The fact that this safer alternative is a different procedure does not render his opinions unreliable or irrelevant to the issues in this case. Dr. Shobeiri's opinions are based upon his medical training, education, clinical experience and peer-reviewed medical literature, including articles addressing the complications related to retropubic mesh slings versus transobturator slings.

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[43] Ex. 3 at 112:5-6.
[44] Ex. 5 at p. 27-29.
[45] Ex. 5 at p. 28-29, n. 28-31.
[46] *Lewis v. Ethicon*, 2014 WL 186869, n. 1 (S.D.W. Va. 2014). This Court subsequently reversed its decision that Plaintiffs in *Lewis* did not have produce evidence of an alternative design under Texas law in *Lewis v. Ethicon*, 2014 WL 457551 (S.D.W. Va. 2014). Despite the reversal on whether proof of an alternative design was required under Texas law, the Court still concluded that the Lewis Plaintiffs had produced "evidence of alternative designs." *Lewis*, 2014 WL 457551 at *3.
[47] Ex. 3 at 81:19 – 86:3.

Finally, Defendants argue that the alternatives proposed by Dr. Shobeiri should be excluded because Dr. Shobeiri has failed to test his theory related to these alternatives. This argument is inexplicable. In Dr. Shobeiri's opinion, a retropubic sling is a safer alternative to a TVT-O and Dr. Shobeiri explains the basis for this opinion.[48] Surely, Defendants, who continuously tout that the Ethicon retropubic TVT is the most studied medical device in history, are not seriously arguing that a retropubic sling has not been tested. Likewise, mesh implanted during abdominal or laparoscopic sacrocolpopexy is a well-documented surgical procedure that has been tested over and over again. Moreover, in his report, Dr. Shobeiri specifically identifies medical literature discussing the advantages of such a procedure over products such as the Prolift.[49]

Defendants' challenge to Dr. Shobeiri's opinions concerning safer alternatives is without merit and Defendants' motion is due to be denied.

III. Dr. Shobeiri is Qualified to Provide Opinions Concerning the Adequacy of Warnings.

Defendants' argument that Dr. Shobeiri is not qualified to testify about the adequacy of warnings provided with Defendants' products is without merit.

Dr. Shobeiri's qualifications and process of evaluating the adequacy of the instructions for use ("IFU") for the Prolift and TVT-O products manufactured by Defendants is similar to the qualifications and process that this Court approved in *Huskey v. Ethicon*. Addressing a Daubert challenge against Dr. Rosenzweig's warning opinions, this Court stated:

> In his expert report, Dr. Rosenzweig states that he has reviewed "numerous" IFUs for a "variety of products including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with the device." . . . . Further, as a urogynecologist, Dr.

[48] Ex. 4 at p. 18-19; Ex. 3 at 81:19 – 86:3, 109:20 – 111:20.
[49] Ex. 5 at p. 28-29, n. 28-31

> Rosenzweig is qualified to opine about the risks of the TVT-O and pelvic mesh surgery and whether those risks were adequately expressed on the TVT-O's IFU. I therefore FIND that Dr. Rosenzweig is qualified to testify generally on the adequacy of the TVT-O's product warnings and marketing materials.[50]

Similarly, this Court approved Dr. Blaivas to testify about warnings for BSC products in *Tyree v. Boston Scientific Corp*.

> [A]s a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU. Dr. Blaivas is qualified to render an opinion as to the completeness and accuracy of Ethicon's warnings and—"it follows from that—the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits" of the TVT-O was when the warnings were published. [51]

In *In re Yasmin and Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, *11-*13 (S.D.Ill.2011), the drug manufacturer argued that the plaintiffs' proffered experts, both obstetrician-gynecologists ("OB/GYN"), were not qualified to offer opinions regarding the adequacy of its labeling, and further that their opinions were not based on any reliable methodology. The Court rejected its argument, and held instructively as to one of the OB-GYN experts as follows:

> As a practicing OB/GYN tasked with making prescription decisions on a daily basis, Dr. Bercy-Roberson is qualified to opine as to how certain knowledge,

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[50] *Huskey v. Ethicon, Inc.*, 2014 WL 3362264 at *5 (S.D. W. Va. July 8, 2014)).

[51] *Tyree*, 2014 WL 5320566 at * 47 (quoting *Huskey*, 2014 WL 3362264 at *20). *See also Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F. Supp. 2d 684, 702 (W.D.N.C. 2003) (citing *In re: Diet Drug* MDL PTO 1332, where the MDL court concluded physicians are "qualified to render an opinion as to the labels' completeness, accuracy, and . . . the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits . . . are or were at the time the labeling was published." *In re: Diet Drug* MDL PTO 1332 at p. 27-28); *Grobelny v. Baxter Healthcare Corp.*, 2008 WL 2186417, *2 (D.N.J.2008) (holding that toxicologist/pharmacologist could not testify as to adequacy of the warning because "he has no experience with pharmaceutical labels because…he is neither a practicing physician nor a licensed pharmacist," but that the plaintiff's treating physician could testify as to his understanding of the risks of drug in question, and that treating physician's testimony would be helpful for the jury to understand "the characteristics of, and the ordinary knowledge common to, the prescribing physician," as required under New Jersey law).

> obtained through studies, reports, and internal Bayer documents, would have affected her previous prescription-related decisions. Dr. Bercy-Roberson does not require expertise in FDA regulations to opine in this manner, as she does not comment on the conduct of the FDA. Further, doctors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs]…and to compare that knowledge with what was provided in the text of labeling and warnings for FDA approved drugs.' *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, *11 (E.D.Pa. June 20, 2000). Thus, Dr. Bercy-Roberson is qualified to render an opinion as to the drug label's completeness and accurateness. *See id*....
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> Thus, as Dr. Bercy-Roberson's opinion based on peer-reviewed sources and data, her methodology is sound. The correctness of her opinion is left to the trier of fact's determination.[52]

Dr. Shobeiri is qualified to provide opinions about the risks associated with Defendants' Prolift and TVT-O and "whether those risks were adequately expressed" in the Prolift and TVT-O IFUs and "the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits" were when the IFUs were published.

Defendants' claim that Dr. Shobeiri's opinions regarding the inadequacies in the TVT-O and Prolift IFUs lack a reliable basis misrepresents his reports, ignores the bases for his opinions and the methodology employed to reach those opinions.[53] As Dr. Shobeiri notes, the TVT-O IFU does not include: "Severity, frequency, permanence, and responsiveness to treatment are not addressed."[54] As to the Prolift product, Dr. Shobeiri notes that the IFU "should have warned about the potential for the mesh to cord, buckle, wrinkle, deform, and degrade, the potential for permanent pain as a result of the mesh, and the potential of multiple tedious, difficult, and risky

[52] The same holding with respect to the Plaintiffs other proffered OB-GYN expert (Anthony Disciullo) – based on his extensive clinical experience and review of peer-reviewed literature and company documents, he was qualified to offer opinions as to the adequacy of the drug warning label, and his opinions were reliable.
[53] Defendants' Memorandum at p. 8-9.
[54] Ex. 4 at p. 24.

surgeries in the event the mesh needed to be removed."[55] These opinions are based on his clinical experience and medical literature that establishes such complications occur with these products.[56] Contrary to Defendants' assertion, Dr. Shobeiri's opinions concerning the inadequacy of the IFUs have a reliable basis including the medical literature addressing complications arising from mesh slings and pelvic organ prolapse mesh products.[57] Furthermore, Defendants misrepresent Dr. Shobeiri's testimony concerning the use of mesh for SUI.[58] Dr. Shobeiri testified that mid-urethral slings are considered the surgical standard of care but the TVT-O is not a mid-urethral sling based on the implant instructions in the TVT-O IFU.[59]

Dr. Shobeiri's opinions are not based on speculation or on his personal belief. He provides the factual bases for his opinions and the methodology utilized to formulate those opinions. This methodology is consistent with the methodology approved for Dr. Blaivas in *Tyree*. Dr. Shobeiri's methodology to establish these factors also includes consideration of the general body of medical literature that he has read, reviewed and considered throughout his years of practice regarding surgical treatment of pelvic organ prolapse and stress urinary incontinence, and literature addressing risks associated with surgical treatment of pelvic organ prolapse and stress urinary incontinence with transvaginal mesh kits which he has reviewed as a matter of practice since 1996.[60]

Based upon all these reliable sources of information, Dr. Shobeiri opines that the TVT-O IFU is "inadequate to inform doctors and patients of the true risks associated with the TVT-O".[61]

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[55] Ex. 5 at p. 25.
[56] Ex. 4 at p. 24 and n. 25; Ex. 5 at p. 24-27 and n. 26 and 27.
[57] Ex. 4 at p. 24 and n. 25; Ex. 5 at p. 24-27 and n. 26 and 27.
[58] Defendants' Memorandum at p. 9-10.
[59] Ex. 3 at 40:4 – 41:7.
[60] Ex. 4 at p. 24 and n. 25; Ex. 5 at p. 24-27 and n. 26 and 27; Ex. 3 at 113:15 – 114:19.
[61] Ex. 4 at p. 24.

and the Prolift IFU "should have warned about the potential for the mesh to cord, buckle, wrinkle, deform, and degrade, the potential for permanent pain as a result of the mesh, and the potential of multiple tedious, difficult, and risky surgeries in the event the mesh needed to be removed."[62] The principles and methods utilized by Dr. Shobeiri are clear and reliable and his testimony should be admitted.

Defendants' challenge to Dr. Shobeiri's inadequate warning opinions is without merit and their Motion is due to be denied.

IV. Dr. Shobeiri's Opinions Concerning Inadequate Education/Training are Relevant and Reliable.

Defendants' argument that Dr. Shobeiri's opinions concerning inadequate education/training are unreliable and irrelevant is without merit. Defendants' argument concerning Dr. Shobeiri's opinions relating to inadequate education/training by Defendants is a disjointed conglomeration of alleged deficiencies. Defendants' arguments are issues for cross examination and not exclusion under Rule 702 and *Daubert*.

First, Defendants assert that Dr. Shobeiri "never explicitly states that Defendants had the responsibility to educate 'community doctors.'"[63] This argument is specious because, whether obligated or not, Defendants "voluntarily" undertook a duty to provide training to the medical community. Defendants' "voluntary" undertaking of this duty is documented by their own documents, including documents reviewed and considered by Dr. Shobeiri.[64] Defendants established a "Professional Education & Relations Team" and employed regional "professional education development managers to achieve goals of "excellence in physician education" and

[62] Ex. 5 at p. 25.
[63] Defendants' Memorandum at p. 10.
[64] Ex. 5 at p. 30, n. 33; ETH.MESH.00031538-560 (attached as Ex. 14).

"drive procedural adoption through trained surgeons."[65] Defendants held education events in "markets with a large potential for future growth" and with a "strong case for 'return on investment."[66] Defendants established "regional training centers" in several locations across the United States.[67] Defendants also recruited doctors for these training courses with an emphasis on "physicians who have the ability to drive business."[68] Even if Defendants were not obligated to provide such education/training, Defendants actually did provide education/training to physicians. It is axiomatic that, once Defendants had undertaken the responsibility of education/training, Defendants were obligated to provide adequate education/training to the physicians.

Second, unlike some others, Dr. Shobeiri relied on a peer-reviewed published study involving mesh-complications being "self-referred" instead of being referred by the implanting physician.[69] This peer-reviewed article was published as part of a 2012 study of mesh complications conducted in part by Dr. Shobeiri.[70] In addition, Dr. Shobeiri relied on another article that addressed the issue of referrals for complications by the implanting physician.[71] Dr. Shobeiri's opinion that Defendants failed to provide adequate education/training to physicians is based upon his own clinical experience and the peer-reviewed articles documenting that the majority of the patients in that study were "self-referred" instead of being referred by the implanting physicians.

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[65] Ex. 14.
[66] *Id*.
[67] *Id*.
[68] *Id*.
[69] Ex. 4 at p. 16, n. 6; Ex. 5 at p. 16, n. 7; *See* Rostaminia, G., *et al.* (2012). *"Referral pattern for vaginal mesh and graft complications to the University of Oklahoma Pelvic and Bladder Health Clinic."* J Okla State Med Assoc 105(9): 356- 358.
[70] Ex. 4 at p. 16; Ex. 5 at p. 16.
[71] Ex. 3 at 161:22 – 163:21.

Third, Defendants assert that Dr. Shobeiri contradicted himself in his deposition because he testified that information concerning mesh complications was available to "community doctors."[72] The fallacy of this assertion is demonstrated by Dr. Shobeiri's actual testimony. Dr. Shobeiri did not contradict his opinions in his deposition testimony. He explained that, while information may have been available in the medical literature, the medical community was not aware of the complications associated with pelvic mesh products as evidenced by the fact that 75% of the patients involved in the 2012 study he conducted were self-referred and not referred by the implanting physicians.[73] Additionally, his study was conducted in 2012, after the 2008 FDA notice, indicating that implanting physicians were not aware of the complications due to the lack of referrals.[74]

Fourth, Defendants assert that Dr. Shobeiri's opinion concerning clinical studies relating to degradation of the mesh should be excluded because he fails to explain his methodology.[75] Dr. Shobeiri's Prolift report explains that his opinion is based upon both scientific literature concerning degradation of polypropylene mesh, Ethicon's internal documents and his experience in conducting such testing for a pelvic mesh product.

Dr. Shobeiri's opinions are based on a sound methodology and are reliable. Defendants' arguments concerning the 2008 FDA report and whether the mesh was implanted before or after the 2008 FDA report are issues for cross examination and not exclusion of his testimony. To the extent that Defendants argue that Dr. Shobeiri's opinions concerning Ethicon's training program

[72] Defendants' Memorandum at p. 11.
[73] Ex. 3 at 137:21 – 139:6.
[74] Ex. 3 at 140:23 – 141:22.
[75] Defendants' Memorandum at p. 11-12.

and failure to test "merely regurgitates information contained in internal Ethicon documents,"[76] Plaintiffs will address such claims below.

V. Dr. Shobeiri is not Offering Opinions about Defendants' State of Mind or Bad Acts.

Defendants' argument that Dr. Shobeiri is offering opinions concerning Defendants' state of mind or bad acts is without merit.

Simply because Dr. Shobeiri relies in part on corporate documents – which may or may not reflect what Defendants knew or did - to form his opinions regarding the design of TVT-O and Prolift products and the risk information that was conveyed to physicians does not mean he is offering impermissible "state of mind," "intent," or "bad acts" opinions. Dr. Shobeiri's citation to a limited number of Defendants' documents in his expert report falls squarely within the parameters previously recognized by this Court – that, "an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible. . .. . . ."[77] As such, Dr. Shobeiri should be permitted to testify as to his reliance and interpretation of corporate documents that form the bases of his opinions.

For instance, Defendants' knowledge that the "TVT-O sling was associated with more pain than other slings" is one factor which Dr. Shobeiri considered in formulating opinions relating to the adequacy of the warnings provided by the TVT-O IFU.[78] Dr. Shobeiri also considered information in published medical literature in formulating his opinions that relied in

[76] Defendants' Memorandum at p. 12.
[77] *See, Tyree*, 2014 WL 5486694 at *6-7, *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W.Va., 2013) (an expert may testify to a review of internal corporate documents for the purpose of explaining the basis of his opinions).
[78] Ex. 4 at p. 19-26.

part on Defendants' knowledge as revealed by company documents.[79] Defendants' knowledge concerning physician training is a factor considered by Dr. Shobeiri for his opinions relating to inadequate education/training of physicians. Dr. Shobeiri considered Defendants' documents revealing that education events would be "indicated by market analysis" and "must have a strong case for 'Return on Investment'" in formulating his opinions.[80] Dr. Shobeiri reviewed internal company documents to formulate his opinions and should be permitted to "testify as to a review" of these documents to "explain the basis" for his opinions.

Even though Dr. Shobeiri does not offer any "factual narrative," this Court has previously addressed the propriety of same, and its ruling is instructive here:

> I **FIND** that *Liberty Media Corp. v. Vivendi Universal, S.A.* provides the appropriate solution to the situation at hand. 874 F.Supp.2d 169, 174 (S.D.N.Y.2012). The Southern District of New York in *Liberty Media* held:
>
> > [The expert] will not be permitted to exhaustively recount all of the facts of the case.... [The expert] will not be permitted to recount the entire history of Vivendi through the class period. Rather, [the expert] must draw on the facts only as necessary—and in as concise a manner as possible—to support his opinion ... which is based on his experience in corporate valuations. I decline to parse [the expert]'s report paragraph-by-paragraph to determine where the report turns from expert analysis to factual narrative. Rather, I trust plaintiffs' counsel will exercise discretion in allocating trial time and will only present the facts necessary to support [the expert]'s opinion. In the event plaintiffs' counsel fails to exercise appropriate discretion, I will cut off any lengthy factual narrative.[81]

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[79] Ex. 4 at p. 26, n. 26; Ex. 3 at 120:17 – 121:23.

[80] Ex. 5 at p. 30, n. 33.

[81] *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d at 646; *see also Huskey v. Ethicon, Inc.*, 2014 WL 3362264, n. 6 (S.D.W. Va. 2014)("Ethicon argues that some of this testimony is inadmissible evidence of Ethicon's corporate knowledge or state of mind. As I have previously stated, I will not parse expert reports in relation to this objection. However, the parties are cautioned that experts must offer opinions that utilize their 'scientific, technical, or other specialized knowledge.").

Consistent with the Court's instructive ruling, Dr. Shobeiri draws on the important facts of this case, including but not limited to Defendants' internal corporate documents, only as necessary to support his opinion.[82]

Defendants' arguments about "state of mind," "intent," "bad acts" and "factual narratives" are misplaced. Defendants' motion to exclude Dr. Shobeiri's testimony concerning why these documents were important and how the documents form a basis for his opinions is due to be denied.

CONCLUSION

Dr. Shobeiri is qualified to provide the opinions set forth in his expert reports for both the TVT-O and Prolift products. His methodology is sound and his opinions are reliable and fit the facts of these cases. Defendants' motion to exclude Dr. Shobeiri's opinions is due to be denied.

This 9th day of May, 2016.

By: /s/ P. Leigh O'Dell

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[82] Dr. Shobeiri's testimony and citation to corporate documents establish the *fact* of Defendants' knowledge and are based on his own review of Defendants' documents. However, the bases for his opinions are not limited to just Defendants' documents. Instead, he relies upon his review of and knowledge of the literature, treating patients with mesh complications and more than 15 years of practice in the field. His testimony regarding Defendants' documents will help the jury to understand these admissible documents and that the warnings and information provided by Defendants to physicians to utilize during informed consent discussions with patients were incomplete, inadequate and not appropriate.

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ P. Leigh O'Dell
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